Registration and legislation

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Introduction

Legislation has been with us for centuries but we still argue about its necessity and some make a living figuring out ways to circumvent it.

Registration, for the agrichemical industry, is of more recent origin being in existence a little over 50 years. However, we don't argue over its necessity, but do sometimes have some doubts about the manner in which it purports to protect the public interest.

The registration process must be seen as an evolutionary concept which, for the most part, has reflected the desires of the community at large. The earliest scheme was little more than a register of products in the market place and, at the time, the community did not require any thing more.

At this time people still had some rapport with the rural environment and those who produced the food they ate and the fibre they wore. They also appreciated that it was those same people who grew the goods which provided income for Australia.

Times have changed; technology arrived. Migrants swelled the population. Awareness was increased. The rapport with rural Australia dwindled. People had time to worry more about issues that did not include concern for the next meal or piece of clothing.

Fear began to stalk the columns of the newspapers. There were "experts" who said that this or that was causing cancer. On the other side there were "experts" who argued the contrary view.

Regulation by legislation was intended to solve this dilemma. Unfortunately it hasn't. Let us now look at the current regulatory framework and what it does tell us about the chemical tools for agriculture.

In the previous paper Warner (p. 131) provided us with the practical background regarding the development of the formulation, the field screening and evaluation which generates a huge volume of data. This is part of the data package which is presented to the regulatory authorities for assessment prior to the marketing of the product.

Australian registration system

From the beginning the system was State based and varied in complexity and fees. At one stage each State required a separate submission. Each submission was different in content and the quantity required in each section varied.

In 1969 the States and the Commonwealth set up the system of clearance of new actives, new uses for old actives and major changes in formulation prior to registration being granted by a State. A protocol for data requirements was developed.

In the intervening years this system worked remarkably well for all its unwieldiness and bureaucracy and was regarded as one of the best in the world.

Over the past years the move to one national registration has gained momentum and we now have a National Registration Authority (NRA) which is guided by a Board consisting of people representing many facets of the community. Professor Ben Selinger is the Chairman.

The components

The original authorities involved in the registration process have not changed but have been added to in the last two decades.

The Drugs, Poisons Scheduling Standing Committee (DPSC) of the National Health and Medical Research Council (NH&MRC) still deals with the assessment of the hazard of the product as presented to the purchaser.

The Pesticides and Agricultural Chemicals Standing Committee (PACC) of the NH&MRC is still charged with the role of assessing the hazard from residues resulting from use and recommending levels which can legally appear on or in foods. The data required for these two committees comprise some 20% of the total cost.

In more recent times the data relating to Occupational Health and Safety has received more attention.

The data relating to environmental behaviour have increased from a relatively small package to the current status today where it may well be the most important criteria on which further development of the compound rests. These data represent some 25% of the cost of development.

The time frame for development can be from 8–10 years depending on the characteristics of the compound and its potential uses.

The aim

The first registration system aimed to protect the purchaser from poor quality badly labelled product. Slowly the emphasis changed to not only do that but to ensure that the user was given advice on use and safety measures to be taken to protect himself.

In the last decade or so the safety issue has maintained its importance but has been joined by the issue of food safety. This is especially of interest to producers seeking export markets.

Unfortunately it is in this latter area that most of the debate has been centred and in many cases conducted by some with little understanding of the basics of toxicology and probability.

Food safety

Acronyms such as MRL, ADI and NOAEL are essential ingredients in an understanding of the regulatory process which yields our food standards.

The whole structure stands on a basic premise enunciated in the late 16th century which in essence says everything is a poison, only the dose determines when it is poisonous. Put in another way it means there are no safe chemical substances. The dose determines their hazard.

Before residue trials conducted in the field, under the expected conditions of use, have begun the traditional toxicity testing procedure has been largely completed and from these data a number of important benchmarks are established.

The first is the No Observable Adverse Effect Level (NOAEL). It is what it says. A dose that when fed daily for the whole of life is not expected to produce an adverse effect.

This datum level is produced from trials with mice, rats, rabbits and sometimes dogs and therefore some allowance has to be made to extrapolate it to use with humans.

The assessing authorities take a very conservative view and usually take the NOAEL and divide it by 100 to produce what is known as the Acceptable Daily Intake (ADI). This figure, for any given compound, is agreed by all regulatory authorities throughout the world.

From the field trials we know how quickly the compound degrades and can therefore make an assessment of the residue, on any particular food commodity when eaten as part of the normal diet, to which an individual may be exposed. The ADI is the reference point. In Australia a Maximum Residue Level (MRL) is generally set so that at no time is a person likely to be exposed to more than 50% of the ADI for any one compound from all potential sources.

It should also be remembered that these calculations are based on the assumption that every hectare of a particular crop, for instance, is treated with a particular compound. This is, of course, most unlikely although the sales people would be happy if it were true.

The MRL is a legal limit and should not be used as a health limit as much of the media tend to do.

Checks on whether these calculations and assumptions are reasonable are carried out by the regulatory authorities through the national market basket survey and specialized surveys. All export produce is also sampled.

The nett result of this sampling clearly shows that suggestions that our farmers are blatant abusers of these products to be false and misleading. Malicious propaganda of this sort can nullify the efforts of nutritionists and other health professionals who are encouraging the greater consumption of fresh fruit and vegetables for the well being of the community.

Environmental issues

The earliest submissions for registration contained little data on such issues. Today the environmental data package contains information on the effects on terrestrial and aquatic systems, degradation processes and the effects of light and temperature on those processes. Also included is the potential for bioaccumulation and biomagnification as well as the leachability in various soil types. The hazards to beneficial organisms is of high importance to enable compounds to be integrated into pest/crop management systems.

Conclusion

The regulatory system which has evolved in Australia ranks amongst the best in the world for the breadth of the data requirements and the thoroughness of assessment.

The result is the best labelled products in the world which are used to produce the highest quality food and fibre to satisfy our domestic and overseas markets.

Marketing and sales of new products: "The Monsanto experience"

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Getting a dollar return – what's involved?

The product

Key to any successful marketing and sales exercise is having a product or service that has a value that customers are prepared to pay for. In the case of agricultural herbicides it involves having a product which will control weeds that cause an economic loss and therefore will return an economic benefit if used correctly. Of course along with the ability to do the job, the product needs to stand up to the tests of environmental acceptability and the toxicology profile that other speakers have identified.

What Monsanto looks for are products that will control a known problem in large hectare crops at low active ingredients rates per hectare and are extremely safe to use and do not persist in the environment. Other uses and crops may become obvious in screening or field testing.

Assuming we have identified a use for the product in hand and it meets the criteria set for it, what next?

In Monsanto's case, it falls into one of two groups:

i. is the product in question already registered (label expansion) or
ii. is it a new product that needs registration.

The first situation is obviously a cheaper allocation of resources and potentially easier to generate a quicker dollar return. The second situation is more involved and more costly as it often means allocation of resources to a new and more risky venture versus the spending of those resources on expanding the uses of already successful products.

In this case I will use the example of Dimension Herbicide, a summer grass herbicide in turf. This is new minor use chemistry that Monsanto has just received registration for, but it represents the first molecule in a new family of chemistry that has much broader uses. It competed internally for resources against the highly successful Roundup house of brands and products.

To ensure success, Dimension needed to suit our long term business strategy worldwide, and needed allocated resources. This was achieved via employing 1.5 people to oversee all aspects of pre and early post-launch, and also establishing a budget to fund these aspects.

Assessing the market – past, present and future

Monsanto conducted a historical market assessment of the turf production and turf maintenance business. We mapped its growth and attempted via market research to assess it today and to determine where it might be in the future. This gave us the frame work in which to develop and apply a marketing and sales plan for Dimension Herbicide.

For Dimension, we needed to determine a net value for the turf production and turf management industry. Where was summer grass present? Could the market be sub-segmented into say the lawn care operators in suburban areas, turf producers, resort golf courses, public ovals, public turf, etc.? What value did each attribute to their turf? What practices did they employ to control summer grass? Were the segments changing?

Competition

A key element in determining a strategy for a new player in the market is to understand the competition that is, and could be, in your chosen market. Competition analysis included not only other chemicals, but cultural or management practises that could affect summer grass control in turf. We reviewed existing chemistry, and also future chemistries for compounds and practices that may impact on the market.

All these competitors were listed and compared for effectiveness, cost per unit area to the user, likely cost per unit area to produce, profit margins of the distribution network, safety to the turf and user, convenience of use, perceived or real weaknesses in performance. In marketing jargon, we conducted a SWOT analysis.

Market parameters – size, where, who?

How much, where and to whom can we expect to sell our product? How much of this market should we attempt to get and over what time frame will we pursue it? What factors are important in achieving our goals?

Such questions are critical if Monsanto is to determine the amount of product that is made, potential pricing options, early distribution needs etc.

A survey and series of focus groups on acceptability of the product profile was conducted. This allowed the assessment of the likely rate of adoption and who